

Calendar No. 587

111TH CONGRESS
2^D SESSION**S. 3751**

To amend the Stem Cell Therapeutic and Research Act of 2005.

IN THE SENATE OF THE UNITED STATES

AUGUST 5, 2010

Mr. HATCH (for himself, Mr. DODD, Mr. BURR, Mr. REED, Mr. ENSIGN, Mr. FRANKEN, Mrs. HAGAN, Ms. KLOBUCHAR, and Mr. COBURN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

SEPTEMBER 23, 2010

Reported by Mr. HARKIN, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]**A BILL**

To amend the Stem Cell Therapeutic and Research Act of 2005.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Stem Cell Therapeutic
5 and Research Reauthorization Act of 2010”.

1 **SEC. 2. AMENDMENTS TO THE STEM CELL THERAPEUTIC**
 2 **AND RESEARCH ACT OF 2005.**

3 (a) CORD BLOOD INVENTORY.—Section 2 of the
 4 Stem Cell Therapeutic and Research Act of 2005 (42
 5 U.S.C. 274k note) is amended—

6 (1) in subsection (a), by inserting “at least” be-
 7 fore “150,000”;

8 (2) in subsection (c)(3), by inserting “at least”
 9 before “150,000”;

10 (3) in subsection (d)—

11 (A) in paragraph (2), by striking “; and”
 12 and inserting “;”;

13 (B) by redesignating paragraph (3) as
 14 paragraph (5); and

15 (C) by inserting after paragraph (2) the
 16 following:

17 “(3) will provide a plan to increase cord blood
 18 unit collections at collection sites that exist at the
 19 time of application; assist with the establishment of
 20 new collection sites; or contract with new collection
 21 sites;

22 “(4) will annually provide to the Secretary a
 23 plan for, and demonstrate, ongoing measurable
 24 progress toward achieving self-sufficiency of cord
 25 blood unit collection and banking operations; and”;

26 (4) in subsection (e)—

1 (A) in paragraph (1)—

2 (i) by striking “10 years” and insert-
3 ing “a period of at least 10 years begin-
4 ning on the last date on which the recipi-
5 ent of a contract under this section re-
6 ceives Federal funds under this section”;
7 and

8 (ii) by striking the second sentence
9 and inserting “The Secretary shall ensure
10 that no Federal funds shall be obligated
11 under any such contract after the date
12 that is 5 years after the date on which the
13 contract is entered into, except as provided
14 in paragraphs (2) and (3).”;

15 (B) in paragraph (2)—

16 (i) in the matter preceding subpara-
17 graph (A)—

18 (I) by striking “Subject to para-
19 graph (1)(B), the” and inserting
20 “the”; and

21 (II) by striking “3” and inserting
22 “5”;

23 (ii) in subparagraph (A)—

24 (I) by inserting “at least” before
25 “150,000”; and

1 (H) by striking “; and” and in-
 2 serting “;”;

3 (iii) in subparagraph (B)—

4 (I) by inserting “meeting the re-
 5 quirements under subsection (d)”
 6 after “receive an application for a
 7 contract under this section”; and

8 (II) by striking “or the Sec-
 9 retary” and all that follows through
 10 the period at the end and inserting “;
 11 or”; and

12 (iv) by adding at the end the fol-
 13 lowing:

14 “(C) the Secretary determines that the
 15 outstanding inventory need cannot be met by
 16 the qualified cord blood banks under contract
 17 under this section.”; and

18 (C) by striking paragraph (3) and insert-
 19 ing the following:

20 “(3) EXTENSION ELIGIBILITY.—A qualified
 21 cord blood bank shall be eligible for a 5-year exten-
 22 sion of a contract awarded under this section, as de-
 23 scribed in paragraph (2), provided that the qualified
 24 cord blood bank—

“(A) demonstrates a superior ability to satisfy the requirements described in subsection (b) and achieves the overall goals for which the contract was awarded;

“(B) provides a plan for how the qualified cord blood bank will increase cord blood unit collections at collection sites that exist at the time of consideration for such extension of a contract, assist with the establishment of new collection sites, or contract with new collection sites; and

“(C) annually provides to the Secretary a plan for, and demonstrates, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations.”;

(5) in subsection (g)(4), by striking “or parent”; and

(6) in subsection (h)—

(A) by striking paragraph (2) and inserting the following:

“(2) AUTHORIZATION OF APPROPRIATIONS.—

There are authorized to be appropriated to the Secretary to carry out the program under this section \$23,000,000 for each of fiscal years 2011 through

2014 and \$20,000,000 for fiscal year 2015. Such funds so appropriated shall remain available until expended.”; and

(B) in paragraph (3), by striking “in each of fiscal years 2007 through 2009” and inserting “for fiscal years 2011 through 2015”.

(b) NATIONAL PROGRAM.—Section 379 of the Public Health Service Act (42 U.S.C. 274k) is amended—

(1) by striking subsection (a)(6) and inserting the following:

“(6) The Secretary, acting through the Advisory Council, shall submit to Congress an annual report on the activities carried out under this section.”;

(2) by striking subsection (d)(2)(D) and inserting the following:

“(D) support studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population, including exploring novel approaches or incentives, such as remote or other innovative technological advances that could be used to collect cord blood units, to expand the number of cord blood unit collection sites partnering with cord blood

1 banks that receive a contract under the Na-
 2 tional Cord Blood Bank Inventory program
 3 under section 2 of the Stem Cell Therapeutic
 4 and Research Act of 2005;” and
 5 (3) by striking subsection (f)(5)(A) and insert-
 6 ing the following:

7 “(A) require the establishment of a system
 8 of strict confidentiality to protect the identity
 9 and privacy of patients and donors in accord-
 10 ance with Federal and State law; and”.

11 (c) AUTHORIZATION OF APPROPRIATIONS.—Section
 12 379B of the Public Health Service Act (42 U.S.C. 274m)
 13 is amended by striking “\$34,000,000” and all that follows
 14 through the period at the end, and inserting “\$30,000,000
 15 for each of fiscal years 2011 through 2014 and
 16 \$33,000,000 for fiscal year 2015. Such funds so appro-
 17 priated shall remain available until expended.”.

18 (d) REPORT ON CORD BLOOD UNIT DONATION AND
 19 COLLECTION.—

20 (1) IN GENERAL.—Not later than 1 year after
 21 the date of enactment of this Act, the Comptroller
 22 General of the United States shall submit to the
 23 Committee on Health, Education, Labor, and Pen-
 24 sions and the Committee on Appropriations of the
 25 Senate, the Committee on Energy and Commerce

1 and the Committee on Appropriations of the House
2 of Representatives, and the Secretary of Health and
3 Human Services a report reviewing studies, dem-
4 onstration programs, and outreach efforts for the
5 purpose of increasing cord blood unit donation and
6 collection for the National Cord Blood Inventory to
7 ensure a high-quality and genetically diverse inven-
8 tory of cord blood units.

9 (2) CONTENTS.—The report described in para-
10 graph (1) shall include a review of such studies,
11 demonstration programs, and outreach efforts under
12 section 2 of the Stem Cell Therapeutic and Research
13 Act of 2005 (42 U.S.C. 274k note) (as amended by
14 this Act) and section 379 of the Public Health Serv-
15 ice Act (42 U.S.C. 274k) (as amended by this Act),
16 including—

17 (A) a description of the challenges and
18 barriers to expanding the number of cord blood
19 unit collection sites, including cost, the impact
20 of regulatory and administrative requirements,
21 and the capacity of cord blood banks to main-
22 tain high-quality units;

23 (B) remote or other innovative techno-
24 logical advances that could be used to collect
25 cord blood units;

1 (C) appropriate methods for improving
2 provider education about collecting cord blood
3 units for the national inventory and participa-
4 tion in such collection activities;

5 (D) estimates of the number of cord blood
6 unit collection sites necessary to meet the out-
7 standing national inventory need and the char-
8 acteristics of such collection sites that would
9 help increase the genetic diversity and enhance
10 the quality of cord blood units collected;

11 (E) best practices for establishing and sus-
12 taining partnerships for cord blood unit collec-
13 tion at medical facilities with a high number of
14 minority births;

15 (F) potential and proven incentives to en-
16 courage hospitals to become cord blood unit col-
17 lection sites and partner with cord blood banks
18 participating in the National Cord Blood Inven-
19 tory under section 2 of the Stem Cell Thera-
20 peutic and Research Act of 2005 and to assist
21 cord blood banks in expanding the number of
22 cord blood unit collection sites with which such
23 cord blood banks partner; and

24 (G) recommendations about methods cord
25 blood banks and collection sites could use to

1 lower costs and improve efficiency of cord blood
 2 unit collection without decreasing the quality of
 3 the cord blood units collected.

4 **SECTION 1. SHORT TITLE.**

5 *This Act may be cited as the “Stem Cell Therapeutic*
 6 *and Research Reauthorization Act of 2010”.*

7 **SEC. 2. AMENDMENTS TO THE STEM CELL THERAPEUTIC**
 8 **AND RESEARCH ACT OF 2005.**

9 (a) *CORD BLOOD INVENTORY.*—Section 2 of the Stem
 10 *Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k*
 11 *note) is amended—*

12 (1) *in subsection (a), by inserting “the inventory*
 13 *goal of at least” before “150,000”;*

14 (2) *in subsection (c)—*

15 (A) *in paragraph (2), by striking “or is*
 16 *transferred” and all that follows through the pe-*
 17 *riod and inserting “for a first-degree relative.”;*
 18 *and*

19 (B) *in paragraph (3), by striking*
 20 *“150,000”;*

21 (3) *in subsection (d)—*

22 (A) *in paragraph (1), by inserting “begin-*
 23 *ning on the last date on which the recipient of*
 24 *a contract under this section receives Federal*
 25 *funds under this section” after “10 years”;*

1 (B) in paragraph (2), by striking “; and”
 2 and inserting “;”;

3 (C) by redesignating paragraph (3) as
 4 paragraph (5); and

5 (D) by inserting after paragraph (2) the fol-
 6 lowing:

7 “(3) will provide a plan to increase cord blood
 8 unit collections at collection sites that exist at the
 9 time of application, assist with the establishment of
 10 new collection sites, or contract with new collection
 11 sites;

12 “(4) will annually provide to the Secretary a
 13 plan for, and demonstrate, ongoing measurable
 14 progress toward achieving self-sufficiency of cord
 15 blood unit collection and banking operations; and”;

16 (4) in subsection (e)—

17 (A) in paragraph (1)—

18 (i) by striking “10 years” and insert-
 19 ing “a period of at least 10 years beginning
 20 on the last date on which the recipient of a
 21 contract under this section receives Federal
 22 funds under this section”; and

23 (ii) by striking the second sentence and
 24 inserting “The Secretary shall ensure that
 25 no Federal funds shall be obligated under

1 *any such contract after the date that is 5*
 2 *years after the date on which the contract is*
 3 *entered into, except as provided in para-*
 4 *graphs (2) and (3).”;*

5 *(B) in paragraph (2)—*

6 *(i) in the matter preceding subpara-*
 7 *graph (A)—*

8 *(I) by striking “Subject to para-*
 9 *graph (1)(B), the” and inserting*
 10 *“The”; and*

11 *(II) by striking “3” and inserting*
 12 *“5”;*

13 *(ii) in subparagraph (A) by striking*
 14 *“150,000” and all that follows through*
 15 *“and” at the end and inserting “the inven-*
 16 *tory goal described in subsection (a) has not*
 17 *yet been met.”;*

18 *(iii) in subparagraph (B)—*

19 *(I) by inserting “meeting the re-*
 20 *quirements under subsection (d)” after*
 21 *“receive an application for a contract*
 22 *under this section”; and*

23 *(II) by striking “or the Secretary”*
 24 *and all that follows through the period*
 25 *at the end and inserting “; or”; and*

1 (iv) by adding at the end the following:

2 “(C) the Secretary determines that the out-
3 standing inventory need cannot be met by the
4 qualified cord blood banks under contract under
5 this section.”; and

6 (C) by striking paragraph (3) and inserting
7 the following:

8 “(3) *EXTENSION ELIGIBILITY.*—A qualified cord
9 blood bank shall be eligible for a 5-year extension of
10 a contract awarded under this section, as described in
11 paragraph (2), provided that the qualified cord blood
12 bank—

13 “(A) demonstrates a superior ability to sat-
14 isfy the requirements described in subsection (b)
15 and achieves the overall goals for which the con-
16 tract was awarded;

17 “(B) provides a plan for how the qualified
18 cord blood bank will increase cord blood unit col-
19 lections at collection sites that exist at the time
20 of consideration for such extension of a contract,
21 assist with the establishment of new collection
22 sites, or contract with new collection sites; and

23 “(C) annually provides to the Secretary a
24 plan for, and demonstrates, ongoing measurable

1 *progress toward achieving self-sufficiency of cord*
 2 *blood unit collection and banking operations.”;*

3 *(5) in subsection (g)(4), by striking “or parent”;*

4 *and*

5 *(6) in subsection (h)—*

6 *(A) by striking paragraphs (1) and (2) and*
 7 *inserting the following:*

8 *“(1) AUTHORIZATION OF APPROPRIATIONS.—*

9 *There are authorized to be appropriated to the Sec-*
 10 *retary to carry out the program under this section*
 11 *\$23,000,000 for each of fiscal years 2011 through*
 12 *2014 and \$20,000,000 for fiscal year 2015.”;*

13 *(B) by redesignating paragraph (3) as*
 14 *paragraph (2); and*

15 *(C) in paragraph (2), as so redesignated, by*
 16 *striking “in each of fiscal years 2007 through*
 17 *2009” and inserting “for each of fiscal years*
 18 *2011 through 2015”.*

19 *(b) NATIONAL PROGRAM.—Section 379 of the Public*
 20 *Health Service Act (42 U.S.C. 274k) is amended—*

21 *(1) by striking subsection (a)(6) and inserting*
 22 *the following:*

23 *“(6) The Secretary, acting through the Adminis-*
 24 *trator of the Health Resources and Services Adminis-*

1 *tration, shall submit to Congress an annual report on*
 2 *the activities carried out under this section.”;*

3 *(2) in subsection (d)—*

4 *(A) in paragraph (2)—*

5 *(i) in the matter preceding subpara-*
 6 *graph (A), by striking “With respect to cord*
 7 *blood, the Program shall—” and inserting*
 8 *the following:*

9 *“(A) IN GENERAL.—With respect to cord*
 10 *blood, the Program shall—”;*

11 *(ii) by redesignating subparagraphs*
 12 *(A) through (H) as clauses (i) through (viii)*
 13 *respectively;*

14 *(iii) by striking clause (iv), as so re-*
 15 *designated, and inserting the following:*

16 *“(iv) support and expand new and ex-*
 17 *isting studies and demonstration and out-*
 18 *reach projects for the purpose of increasing*
 19 *cord blood unit donation and collection*
 20 *from a genetically diverse population and*
 21 *expanding the number of cord blood unit*
 22 *collection sites partnering with cord blood*
 23 *banks receiving a contract under the Na-*
 24 *tional Cord Blood Inventory program under*
 25 *section 2 of the Stem Cell Therapeutic and*

1 *Research Act of 2005, including such studies*
2 *and projects that focus on—*

3 “(I) remote collection of cord
4 blood units, consistent with the re-
5 quirements under the Program and the
6 National Cord Blood Inventory pro-
7 gram goal described in section 2(a) of
8 the Stem Cell Therapeutic and Re-
9 search Act of 2005; and

10 “(II) exploring novel approaches
11 or incentives to encourage innovative
12 technological advances that could be
13 used to collect cord blood units, con-
14 sistent with the requirements under the
15 Program and such National Cord
16 Blood Inventory program goal;”;

17 (iv) by adding at the end the following:

18 “(B) *EFFORTS TO INCREASE COLLECTION*
19 *OF HIGH QUALITY CORD BLOOD UNITS.—In car-*
20 *rying out subparagraph (A)(iv), not later than 1*
21 *year after the date of enactment of the Stem Cell*
22 *Therapeutic and Research Reauthorization Act*
23 *of 2010 and annually thereafter, the Secretary*
24 *shall set an annual goal of increasing collections*
25 *of high quality cord blood units, consistent with*

1 the inventory goal described in section 2(a) of
2 the Stem Cell Therapeutic and Research Act of
3 2005 (referred to in this subparagraph as the
4 ‘inventory goal’), and shall identify at least one
5 project under subparagraph (A)(iv) to replicate
6 and expand nationwide, as appropriate. If the
7 Secretary cannot identify a project as described
8 in the preceding sentence, the Secretary shall
9 submit a plan, not later than 180 days after the
10 date on which the Secretary was required to
11 identify such a project, to the Committee on
12 Health, Education, Labor, and Pensions of the
13 Senate and the Committee on Energy and Com-
14 merce of the House of Representatives for ex-
15 panding remote collection of high quality cord
16 blood units, consistent with the requirements
17 under the National Cord Blood Inventory pro-
18 gram under section 2 of the Stem Cell Thera-
19 peutic and Research Act of 2005 and the inven-
20 tory goal. Each such plan shall be made avail-
21 able to the public.

22 “(C) *DEFINITION.*—In this paragraph, the
23 term ‘remote collection’ means the collection of
24 cord blood units at locations that do not have

1 *written contracts with cord blood banks for col-*
 2 *lection support.”; and*

3 *(B) in paragraph (3)(A), by striking*
 4 *“(2)(A)” and inserting “(2)(A)(i)”;* and
 5 *(3) by striking subsection (f)(5)(A) and inserting*
 6 *the following:*

7 *“(A) require the establishment of a system*
 8 *of strict confidentiality to protect the identity*
 9 *and privacy of patients and donors in accord-*
 10 *ance with Federal and State law; and”.*

11 *(c) ADDITIONAL REPORTS.—*

12 *(1) INTERIM REPORT.—In addition to the an-*
 13 *nual report required under section 379(a)(6) of the*
 14 *Public Health Service Act (42 U.S.C. 274k(a)(6)), the*
 15 *Secretary of Health and Human Services (referred to*
 16 *in this subsection as the “Secretary”), in consultation*
 17 *with the Advisory Council established under such sec-*
 18 *tion 379, shall submit to Congress an interim report*
 19 *not later than 180 days after the date of enactment*
 20 *of this Act describing—*

21 *(A) the methods to distribute Federal funds*
 22 *to cord blood banks used at the time of submis-*
 23 *sion of the report;*

1 (B) how cord blood banks contract with col-
 2 lection sites for the collection of cord blood units;
 3 and

4 (C) recommendations for improving the
 5 methods to distribute Federal funds described in
 6 subparagraph (A) in order to encourage the effi-
 7 cient collection of high-quality and diverse cord
 8 blood units.

9 (2) *RECOMMENDATIONS.*—Not later than 1 year
 10 after the date of enactment of this Act, the Advisory
 11 Council shall submit recommendations to the Sec-
 12 retary with respect to—

13 (A) whether models for remote collection of
 14 cord blood units should be allowed only with lim-
 15 ited, scientifically-justified safety protections;
 16 and

17 (B) whether the Secretary should allow for
 18 cord blood unit collection from routine deliveries
 19 without temperature or humidity monitoring of
 20 delivery rooms in hospitals approved by the
 21 Joint Commission.

22 (d) *AUTHORIZATION OF APPROPRIATIONS.*—Section
 23 379B of the Public Health Service Act (42 U.S.C. 274m)
 24 is amended by striking “\$34,000,000” and all that follows
 25 through the period at the end, and inserting “\$30,000,000

1 *for each of fiscal years 2011 through 2014 and \$33,000,000*
 2 *for fiscal year 2015.”.*

3 *(e) REPORT ON CORD BLOOD UNIT DONATION AND*
 4 *COLLECTION.—*

5 *(1) IN GENERAL.—Not later than 1 year after*
 6 *the date of enactment of this Act, the Comptroller*
 7 *General of the United States shall submit to the Com-*
 8 *mittee on Health, Education, Labor, and Pensions*
 9 *and the Committee on Appropriations of the Senate,*
 10 *the Committee on Energy and Commerce and the*
 11 *Committee on Appropriations of the House of Rep-*
 12 *resentatives, and the Secretary of Health and Human*
 13 *Services a report reviewing studies, demonstration*
 14 *programs, and outreach efforts for the purpose of in-*
 15 *creasing cord blood unit donation and collection for*
 16 *the National Cord Blood Inventory to ensure a high-*
 17 *quality and genetically diverse inventory of cord*
 18 *blood units.*

19 *(2) CONTENTS.—The report described in para-*
 20 *graph (1) shall include a review of such studies, dem-*
 21 *onstration programs, and outreach efforts under sec-*
 22 *tion 2 of the Stem Cell Therapeutic and Research Act*
 23 *of 2005 (42 U.S.C. 274k note) (as amended by this*
 24 *Act) and section 379 of the Public Health Service Act*

1 (42 U.S.C. 274k) (as amended by this Act), includ-
2 ing—

3 (A) a description of the challenges and bar-
4 riers to expanding the number of cord blood unit
5 collection sites, including cost, the cash flow re-
6 quirements and operations of awarding con-
7 tracts, the methods by which funds are distrib-
8 uted through contracts, the impact of regulatory
9 and administrative requirements, and the capac-
10 ity of cord blood banks to maintain high-quality
11 units;

12 (B) remote collection or other innovative
13 technological advances that could be used to col-
14 lect cord blood units;

15 (C) appropriate methods for improving pro-
16 vider education about collecting cord blood units
17 for the national inventory and participation in
18 such collection activities;

19 (D) estimates of the number of cord blood
20 unit collection sites necessary to meet the out-
21 standing national inventory need and the char-
22 acteristics of such collection sites that would help
23 increase the genetic diversity and enhance the
24 quality of cord blood units collected;

1 (E) best practices for establishing and sus-
2 taining partnerships for cord blood unit collec-
3 tion at medical facilities with a high number of
4 minority births;

5 (F) potential and proven incentives to en-
6 courage hospitals to become cord blood unit col-
7 lection sites and partner with cord blood banks
8 participating in the National Cord Blood Inven-
9 tory under section 2 of the Stem Cell Thera-
10 peutic and Research Act of 2005 and to assist
11 cord blood banks in expanding the number of
12 cord blood unit collection sites with which such
13 cord blood banks partner;

14 (G) recommendations about methods cord
15 blood banks and collection sites could use to
16 lower costs and improve efficiency of cord blood
17 unit collection without decreasing the quality of
18 the cord blood units collected; and

19 (H) a description of the methods used prior
20 to the date of enactment of this Act to distribute
21 funds to cord blood banks and recommendations
22 for how to improve such methods to encourage
23 the efficient collection of high-quality and diverse
24 cord blood units, consistent with the require-
25 ments of the C.W. Bill Young Cell Transplan-

1 *tation Program and the National Cord Blood In-*
2 *ventory program under section 2 of the Stem*
3 *Cell Therapeutic and Research Act of 2005.*

4 (f) *DEFINITION.—In this Act, the term “remote collec-*
5 *tion” has the meaning given such term in section*
6 *379(d)(2)(C) of the Public Health Service Act.*

Calendar No. 587

11TH CONGRESS
2^D Session

S. 3751

A BILL

To amend the Stem Cell Therapeutic and Research
Act of 2005.

SEPTEMBER 23, 2010

Reported with an amendment